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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,014

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Clint Chapple

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EXAMINER

PAGE, BRENT T

ART UNIT

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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,014	Applicant(s) CHAPPLE ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending and examined herein on the merits.

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 is missing the period at the end of the claim and appears to be truncated. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Nikolau et al (US20020162137, filed June 25, 1999).

The claims are drawn to a plant or plant seed comprising a heterologous nucleic acid sequence wherein the expression of the heterologous sequence decreases activity of REF1 in said plant or plant seed, resulting in reduced sinapine content, hydroxycinnamic acid content and ferulic acid content, as well as a method comprising treating a plant or plant seed wherein the treatment

Art Unit: 1638

decreases expression of a REF1 gene, and growing said treated seed or plant, wherein the heterologous nucleic acid product interferes with expression of REF1 and wherein sinapine, hydroxycinnamic acid and ferulic acid content are reduced.

Nikolau teach the transformation of plants with nucleic acid constructs comprising antisense oriented sequences that encode aldehyde dehydrogenase or ribozymes that cleave a molecule encoding aldehyde dehydrogenase (see claims 47, 63, 84-86, 88, 91, 94 and 97, for example) and the plant and plant parts therefrom wherein the enzyme level of aldehyde dehydrogenase is decreased. According to the instant specification, on page 8, "REF1" refers to an aldehyde dehydrogenase with activity toward hydroxycinnamic acid, and is represented by SEQ ID NO:1 (see page 32 of the specification last paragraph for example). The aldehyde dehydrogenase encoded by SEQ ID NO:21, taught by Nikolau et al has a sequence of identity of 99.2% with that of SEQ ID NO:1, with a single mismatch. This sequence is from Arabidopsis and is therefore considered to be the REF1 gene absent evidence to the contrary. Nikolau et al teach all the limitations and method steps of the instant claims and would therefore inherently decrease sinapine content, hydroxycinnamic content and ferulic acid content (which is a hydroxycinnamic acid). It is known in the art that aldehyde dehydrogenase acts on hydroxycinnamic acid, and this knowledge is therefore the basis of the inherency. The method step of growing the treated plant is taught by Nikolau et al in paragraph 105 as well as inherently in Example 10 where different plant developmental stages are studied. Nikolau et al also

Art Unit: 1638

teach that the method is useful in the alteration of acetyl CoA levels in plants including canola and brassica (see paragraph 117 where canola, rapeseed and Arabidopsis are all listed as plants of the invention).

Accordingly, claims 1-16 are rejected under 35 USC 102(e) as being anticipated by Nikolau et al (US20020162137).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nikolau et al (US20020162137) in view of Keller et al (US Patent 6703539).

The claims are drawn to a plant or plant seed comprising a heterologous nucleic acid sequence wherein the expression of the heterologous sequence decreases activity of REF1 in said plant or plant seed, resulting in reduced sinapine content, hydroxycinnamic acid content and ferulic acid content, as well as a method comprising treating a plant or plant seed wherein the treatment decreases expression of a REF1 gene, and growing said treated seed or plant, wherein the heterologous nucleic acid product interferes with expression of REF1 and wherein sinapine, hydroxycinnamic acid and ferulic acid content are reduced and wherein the plant is *Brassica napus* or canola.

Nikolau teach the transformation of plants with nucleic acid constructs comprising antisense oriented sequences that encode aldehyde dehydrogenase or ribozymes that cleave a molecule encoding aldehyde dehydrogenase (see claims 47, 63, 84-86, 88, 91, 94 and 97, for example) and the plant and plant parts therefrom wherein the enzyme level of aldehyde dehydrogenase is decreased. According to the instant specification, on page 8, "REF1" refers to an aldehyde dehydrogenase with activity toward hydroxycinnamic acid, and is represented by SEQ ID NO:1 (see page 32 of the specification last paragraph for example). The aldehyde dehydrogenase encoded by SEQ ID NO:21, taught by Nikolau et al has a sequence of identity of 99.2% with that of SEQ ID NO:1, with a single mismatch. This sequence is from Arabidopsis and is therefore considered to be the REF1 gene absent evidence to the contrary. Nikolau et al teach all the limitations and method steps of the instant claims and therefore it naturally follows that sinapine, hydroxycinnamic acid and ferulic acid content would be decreased in the transformed plants. Nikolau et al also teach that the method is useful in the alteration of acetyl CoA levels in plants including canola (see paragraph 117).

Although Nikolau teaches canola in paragraph 117 of the specification, and thus meets the limitations of claims 5-7, Nikolau does not specifically claim canola, nor use it in the working examples. However, even if these limitations arguably were not taught, there is sufficient motivation in the art to use canola plants as suggested by Nikolau.

Art Unit: 1638

For example, Keller et al (US Patent 6703539, filed January 22, 1999) teach genetically altering a canola plant having reduced sinapine content by transforming the plant with a nucleic acid construct comprising a nucleic acid encoding a betaine aldehyde dehydrogenase (see claims 1, 3, 6, 8 and 10, for example). Keller et al also teach that sinapine is a bitter flavored anti-nutritional compound (see the 17th paragraph under Detailed Description of the Invention, for example).

Given the state of the art and the disclosures by Nikolau et al and Keller et al, one of ordinary skill in the art would have been motivated to practice the method taught by Nikolau et al on canola plants as suggested by Nikolau to alter acetyl CoA levels. It naturally follows that once motivated to practice the invention on canola plants or seeds that the limitations of all the claims are met. One of ordinary skill in the art would have been further motivated to alter secondary metabolites in canola as taught by Keller because of the anti-nutritional effects of secondary metabolites. Keller also establishes that one of ordinary skill in the art would have had a reasonable expectation of success in transforming canola with the constructs that alter secondary metabolites. Accordingly the claims are obvious under USC 103(a) over Nikolau et al in view of Keller et al.

No claims are free of the prior art.

No claims are allowed.

Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/
Supervisory Patent Examiner, Art Unit 1638